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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Leonard Kohn, et al. : Paper No:
Serial No. 09/151,612 : Group Art Unit: 1632
Filed: September 11, 1998 : Examiner: Quang Nguyen
For: IMMUNE ACTIVATION BY DOUBLE-STRANDED POLYNUCLEOTIDES

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

THE ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Dear Sir:

In accordance with 37 C.F.R. §§1.97 and 1.98, Applicant herewith submits certain patent references and other information, which the Patent & Trademark Office may wish to consider in examining the above-identified application. The references and information are provided below, and are also listed on the attached Form PTO-1449.

REFERENCES

Naoki Shimojo, et al., "*Induction of Graves-like disease in mice by immunization with fibroblasts transfected with the thyrotropin receptor and a class II molecule*", Proc. Natl. Acad. Sci. U.S.A. 93:11074-11079 (1996)

Ken-Ichi Yamaguchi, et al., "*Genetic Control of Anti-Thyrotropin Receptor Antibody Generation in H-2^K Mice Immunized with Thyrotropin Receptor-Transfected Fibroblasts*", J. Clin. Endocrinol. Metab. 82:4266-4269 (1997)

Shuichi Kikuoka et al., "*The Formation of Thyrotropin Receptor (TSHR) Antibodies in a Graves' Animal Model Requires the N-Terminal Segment of the TSHR Extracellular Domain*", Endocrinology 139:1891-1898 (1998)

M. Kita, et al., "*Regulation and Transfer of a Murine Model of Thyrotropin Receptor Antibody Mediated Graves' Disease*", Endocrinology 140:1392-1398 (1999)

Ken J. Ishii, et al., "*Genomic DNA Released by Dying Cells Induces the Maturation of APCs^{1,2}*", The Journal of Immunology, 2602-2607 (2001)

Joanne M. Heward, et al., "*The Development of Graves' Disease and the CTLA-4 Gene on Chromosome 2q33*", J. Clin. Endocrinol. Metab. 84:2398-2401 (1999)

- Yaron Tomer, et al., "*Mapping the Major Susceptibility Loci for Familial Graves' and Hashimoto's Diseases: Evidence for Genetic Heterogeneity and Gene Interactions*", Clin. Endocrinol. Metab. 84:4656-4664 (1999)
- Yaron Tomer et al., "*Infection, Thyroid Disease, and Autoimmunity*", Endocr. Rev. 14:107-121 (1993)
- Monica Molteni et al., "*High Frequency of T-Cell Lines Responsive to Immunodominant Epitopes of Thyrotropin Receptor in Healthy Subjects*", 8:241-247 (1998)
- Monica Molteni et al., "*CD8+ cell-mediated induction of anergy in TSHR-specific clones*" (In Press)
- T.F. Davies et al., "*Evidence of limited variability of antigen receptors on intrathyroidal T cells in autoimmune thyroid disease*"; N. Engl. J. Med. 325:238-244 (1991)
- Tatsuo Yanagawa et al., "*Human Histocompatibility Leukocyte Antigen-DQA1*0501 Allele Associated with Genetic Susceptibility to Graves' Disease in a Caucasian Population*", J. Clin. Endocrinol. Metab. 76:1569-1574 (1993)
- A.B.T. Barlow et al., "*Association of HLA-DQA1*0501 with Graves' disease in English Caucasian men and women*"; Clin. Endocrinol. (Oxf.) 44:73-77 (1996)
- Juan Carlos Jaume et al., "*Cellular Thyroid Peroxidase (TPO), Unlike Purified TPO and Adjuvant, Induces Antibodies in Mice that Resemble Autoantibodies in Human Autoimmune Thyroid Disease*", J. Clin. Endocrinol. Metab. 84:1651-1657 (1999)
- Leonard D. Kohn, et al., "*An Animal Model of Graves' Disease: Understanding the Cause of Autoimmune Hyperthyroidism*"; Endocrine & Metabolic Disorders 1:59-67 (2000)
- Leonard D. Kohn, et al., "*Graves' Disease: A Host Defense Mechanism Gone Awry*"; Intern. Rev. Immunol. 19:633-664 (2000)
- Masako Kita-Furuyama, et al., "*Dendritic Cells Infected with Adenovirus Expressing the TSH Receptor Induce Graves' Hyperthyroidism in BALB/c Mice*"; Endocrinology Journal (In Press)

Copies of the listed references are provided. No representation is made or intended that a prior art search has been made or that no better art than the listed is available. It is respectfully requested that the information be considered by the Examiner and made of record in the present application.

Serial No. 09/151,612

The Assistant Commissioner for Patents is authorized to charge any deficiency or credit any overpayment to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully submitted,

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